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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,790	09/22/2005	Toshihisa Nakamura	1029650-000161	3076
21839	7590	11/27/2009		EXAMINER
BUCHANAN, INGERSOLL & ROONEY PC				FOREMAN, JONATHAN M.
POST OFFICE BOX 1404				
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
				3736
			NOTIFICATION DATE	DELIVERY MODE
			11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,790	<b>Applicant(s)</b> NAKAMURA ET AL.
	<b>Examiner</b> JONATHAN ML FOREMAN	<b>Art Unit</b> 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 September 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 28-57 is/are pending in the application.  
 4a) Of the above claim(s) 43-57 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 28-32 and 35-42 is/are rejected.  
 7) Claim(s) 33 and 34 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 9/22/05/4/3/07/7/16/07.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the abstract exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

### ***Election/Restrictions***

3. Applicant's election of Group I in the reply filed on 9/8/09 is acknowledged. Applicant's election failed to include and indication of the election being made with or without traverse. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 43 – 57 are withdrawn from consideration.

***Information Disclosure Statement***

4. The information disclosure statements filed 9/22/05, 4/3/07 and 7/16/07 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

***Note to Applicant Regarding 35 USC § 112 6<sup>th</sup> Paragraph***

5. In regards to claim 28 , only those claims using “means for” or “step for” modified by some functional language, as long as it is not modified by sufficient structure, material, or acts for achieving the specified function, will invoke 112.6<sup>th</sup> paragraph. In the present case “means to prevent said body fluid from infiltrating into other parts than said measuring part” has not been considered by the Examiner as invoking 112.6<sup>th</sup> paragraph.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 28 – 32, 35 – 37, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,506,168 Fathallah et al.

In regard to claims 28 – 32, 35 – 37, 40 and 42, Fathallah et al. disclose a body fluid collecting device (Figure 1A) including a sensor (28) to detect a prescribed component in the body fluid, wherein the sensor includes at its distal end a measuring part capable of holding the body fluid (Col. 9, lines 11 – 12), and the body fluid collecting device includes a first supporter (Portion of 24

where sensor (28) rests) to support the vicinity of the measuring part of the sensor and a second supporter (36) to support the sensor at a place closer to the proximal end than the first supporter (Figure 1A), and also includes means to prevent the body fluid from infiltrating into other parts than the measuring part(Col. 8, line 55; Col. 9, lines 54 – 58). The first supporter is arranged closer to the central axis of the body fluid collecting device than the second supporter (Figure 1A). The sensor electrically detects the prescribed component in the body fluid by contact with the body fluid (Col. 8, line 66 – Col. 9, line 2; Col. 9, lines 14 – 18). Fathallah et al. disclose a non-contact space between the first and second supporters forming a non-contact space in which the surface of the sensor does not substantially come into contact with the inside of the body fluid collecting device. This can be seen in Figure 1A on the bottom side of sensor (28). A portion of the sensor is bent in the non-contact space and is inclined with respect to a lengthwise direction of a body fluid duct (24) which communicates with the first supporter and introduces body fluid into the measuring part (Figure 1A).

8. Claims 28 is rejected under 35 U.S.C. 102(e) as being anticipated by 7,264,627 to Perez.

In regard to claims 28, Perez discloses a body fluid collecting device (Figures 14 – 17) including a sensor (124) to detect a prescribed component in the body fluid, wherein the sensor includes at its distal end a measuring part capable of holding the body fluid (Col. 12, lines 57 – 60), and the body fluid collecting device includes a first supporter (122) to support the vicinity of the measuring part of the sensor and a second supporter (123) to support the sensor at a place closer to the proximal end than the first supporter, and also includes means to prevent the body fluid from infiltrating into other parts than the measuring part (126, 131; Col. 13, lines 14 – 17).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 38, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,506,168 Fathallah et al.

In regard to claims 38 and 39, Fathallah et al. disclose a body fluid duct (24) which communicates with the first supporter and introduces body fluid into the measuring part. However, Fathallah et al. fail to disclose the volume of the fluid duct or the length and inside diameter of the fluid duct. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In the present case, one having ordinary skill in the art would be motivated to modify the fluid duct disclosed by Fathallah et al. to have the claimed volume and dimensions or any size as desired in order to maximize or minimize the flow of body fluid into the measuring part as desired.

In regard to claim 41, Fathallah et al. disclose a guide (20) that projects from the distal end of the body fluid collecting device and introduces body fluid into the inlet opening of the body fluid duct (24). However, Fathallah et al. fail to disclose the distance from the distal end of the guide to the inlet of the body fluid duct being 1 to 10 mm. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In the present case, one having ordinary skill in the art would be motivated to modify

the fluid duct disclosed by Fathallah et al. to have the claimed volume and dimensions or any size as desired in order to maximize or minimize the flow of body fluid into the measuring part as desired.

***Allowable Subject Matter***

11. Claims 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to disclose the first supporter having at its proximal end a concave that communicates with the non-contact space.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan ML Foreman/  
Examiner, Art Unit 3736